UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,750	05/03/2007	Justin P. Phillips	45852-P001WOUS	7003

61060 7590 07/01/2009

WINSTEAD PC
P.O. BOX 50784
DALLAS, TX 75201

EXAMINER	
BERHANU, ETSUB D	
ART UNIT	PAPER NUMBER
3768	
MAIL DATE	DELIVERY MODE
07/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,750	PHILLIPS ET AL.	
	Examiner	Art Unit	
	ETSUB D. BERHANU	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-13,15 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-13, 15, 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

2. Claims 9-12, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al.'774 (previously cited) further in view of Sperinde'248 (USPN 4,623,248).

Miller et al.'774 discloses an apparatus and method for monitoring local cerebral physiology (see TITLE), wherein the apparatus comprises an oximetry probe, a cranial access bolt and means for supporting optical fibers of the apparatus (col. 8, lines 28-55 and col. 14, line 65 – col. 15, line 4) and the method is capable of measuring an oxygen saturation level of the brain by inserting the apparatus into the cranial access bolt (see ABSTRACT, col. 5, lines 20-24 and col. 13, lines 17-37). Miller et al.'774 discloses all the elements of the current invention except for the details of the oximetry probe, specifically a first monochromatic light source, a second monochromatic light source, a first and second optical fiber, a receiver, means for determining the oxygen saturation level of the blood and means for pulsing each light source. Figure 4 of Sperinde'248 teaches an invasive oximeter probe comprising a first monochromatic light source 4, a second monochromatic light source 6, a first optical fiber 26 for transferring light from at least one light source to an internal measurement site, a receiver 32, a second optical fiber 28 for transferring light reflected from the measurement site to the receiver, means 9 for pulsing the light from the first and second light sources sequentially along the first fiber and means 74 for determining the oxygen saturation level of the blood at the internal measurement site based on the light produced by the light sources and the light received by the receiver (see Figure 4 and description thereof). It would have been within the skill of the art to use the oximetry probe of Sperinde'248 as the oximetry probe of Miller et al.'774 since Miller et al.'774 discloses an invasive oximetry probe, but fails to give the

details of the oximetry probe, and Sperinde'248 discloses the details of an optical oximetry probe that is capable of being used as the oximetry probe of Miller et al.'774. Regarding the limitation in claim 9 (there is no claim with this number) that the optical centers of the first and second optical fibers are separated from one another by at least 1mm at their distal ends, it is noted that the Applicant has failed to provide criticality or unexpected results for this distance in the Specification. Therefore, it would have been within the skill of the art, through due experimentation, to realize an optimal distance between the distal ends of the first and second optical fibers to obtain the most accurate saturation level measurements.

3. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al.'774 further in view of Sperinde'248, as applied to claim 9, further in view of Casciani et al.'363 (USPN 6,272,363).

Miller et al.'774 further in view of Sperinde'248 discloses all the elements of the current invention, as discussed in paragraph 2 above, except for the specific wavelengths emitted by the light sources. Casciani et al.'363 discloses that conventional pulse oximeters emit light at red and infrared wavelengths, wherein the red wavelength is near 660nm and wherein the infrared wavelength is in the range of 880nm to 940nm (col. 1, lines 50-54). It would have been within the skill of the art to modify the light sources of Miller et al.'774 further in view of Sperinde'248 to produce light having a peak emission wavelength of 660nm and between 820nm to 930nm, as taught by Casciani et al.'363, since Sperinde'248 discloses that light sources are used to produce different wavelengths of light capable of providing a tissue oxygenation measurement, but fails to give details of the wavelengths, and Casciani et al.'363 teaches wavelength values well known in the art for conventional tissue oximetry measurements.

Response to Arguments

4. Applicant's arguments, see the Remarks, filed 15 April 2009, with respect to the rejection of claims 9-16 via Keller further in view of Miller have been fully considered and are persuasive. The rejection of claims 9-16 with respect to Keller further in view of Miller has been withdrawn. Applicant's

arguments with respect to the rejection of claims 9-16 with Miller further in view of Keller have been fully considered but they are not persuasive. Applicant argues on pages 8 and 9 of the Remarks that Miller teaches a Doppler flowmetry sensor and does not teach an oximetry probe. Examiner would like to draw the Applicant's attention to the ABSTRACT of the Miller reference, which explicitly states that "In another embodiment, a combined probe includes a tissue oxymetry probe...", to col. 5, lines 20-24 which states that "In another embodiment, a combined probe includes a tissue oxymetry probe...", and col. 13, lines 17-37 which states that "a conventional tissue oxymetry probe... may be included into the combined probe or substituted for the ICP probe.", each of which was cited in the previously mailed Office Action. Therefore, Miller does in fact disclose a tissue oximetry probe. However, for the reasons argued against combining Keller and Miller discussed on page 8 of the Remarks, the rejection of claims 9-16 with respect to Miller further in view of Keller have been withdrawn, and a new rejection of claims 9-16 with Miller and Sperinde, and further with Casciani (Claim 13) has been made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ETSUB D. BERHANU whose telephone number is (571)272-6563. The examiner can normally be reached on Monday - Friday (7:00 - 3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

EDB